REMARKS/ARGUMENTS

Claim Objections

The Examiner has objected to claim 12 because the term "psychostimulants" is mistyped. Claim 12 has been amended to correct this typographical error.

35 U.S.C. §103(a) Lundy et al. (WO 1998/050033) in view of Sparks et al. (US 5,354,556)

Claims 1 and 6-11 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Lundy et al. (WO 1998/050033) in view of Sparks et al. (US 5,354,556). In making this rejection the Examiner states that Lundy et al. teach chewable oral tablets comprising carprofen which may be in multiparticulate form, in a sustained release formulation, but that Lundy et al. do not expressly teach the coating materials for the mutiparticulate form. The Examiner further states that Sparks et al. teach coated materials to obtain controlled release microparticles.

Lundy et al. mention sustained release formulations and microparticles for example on page 14 lines 14-17, page 19 line 24, and page 39 line 14. However Lundy et al. do not teach coating such particles to achieve sustained release. On page 62 Lundy et al. state that controlled release oral formulations are preferred, but provide no indication of how such formulations could be prepared. Thus, Lundy et al. indicate the desirability of controlled release, but provide no teaching of coating microparticles to achieve such controlled release.

The coating method of Sparks et al. is not the same as that of the Applicants. Sparks et al. relate to microparticles "in the form of a micromatrix of an active ingredient uniformly distributed in at least one non-toxic polymer." (Abstract) This is distinctly different from Applicants' invention in which the particles are formed and then coated with a polymer (page 3 line 37). To help visualize the difference one can imagine that the composition of Sparks et al. is analogous to peanut brittle in which peanuts are uniformly distributed in a matrix of caramel and sugar while Applicants' composition is analogous to individual peanuts coated in a caramel sugar coating. Even if exactly the same coating material is used, it is clear that peanut brittle is not the same as a candied peanut. The microparticles of Sparks et al. are equally different from Applicants' microparticles. Drug product uniformly distributed in a matrix will release relatively evenly as the matrix breaks down. As set forth on page 5 lines 5-14 of the specification,

Applicants' invention can provide sustained release, delayed release, or pulsatile release. A particle of a drug ingredient coated with a polymer releases nothing until the polymer breaks down sufficiently to allow body fluids to contact the drug particle whereupon release is fairly rapid. Such polymer coated drug particles provide sustained release when particles having a variable degree of polymer coating are combined. Such particles provide delayed release if the composition has particles with a constant polymer coating of adequate thickness. Finally, such particles provide pulsatile release if particles having a constant thin polymer coat are combined with particles having a constant thicker coat. Thus, the microparticles of Sparks et al. are not the same as those used in Applicants' invention. The combination of Sparks et al. and Lundy et al. does not lead to the composition used in Applicants' invention. Reconsideration and withdrawal of this rejection is respectfully requested.

35 U.S.C. §103(a) Lundy et al. (WO 1998/050033) in view of Jans et al. (US 5,824,336)

Claims 1 and 13-17 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Lundy et al. (WO 1998/050033) in view of Jans et al. (US 5,824,336). The Lundy application is discussed above. Jans et al. relate to flavored tablets. Jans et al. provide no teaching about controlled release or microparticles. Accordingly, the combination of Lundy et al. and Jans et al. does not lead to Applicants' invention. Reconsideration and withdrawal of this rejection is respectfully requested.

35 U.S.C. §103(a) Lundy et al. (WO 1998/050033) in view of Sparks et al. (US 5,354,556) and further in view of Jans et al. (US 5,824,336)

Claims 1, 18-22, and 24-27 are rejected. As discussed above, Lundy et al. do not disclose coated microparticles. Sparks et al. relate to microparticles containing a drug substance uniformly distributed in a matrix, and does not relate to coated microparticles. Jans et al. relate to flavored tablets. Nowhere in this combination is there a teaching of coated microparticles. Taken together, these references do not lead to Applicants' invention. Reconsideration and withdrawal of this rejection is respectfully requested.

With regard to claims 18 and 19 the Examiner alleges that it involved no more than routine experimentation to find the proper coating percentage and level of the palatability improving agent. Applicants respectfully disagree. The claims are directed to a palatability agent in combination with a coated microparticle. As set forth above, this combination is not rendered obvious by the cited references. The addition of the composition percentages does not render obvious these claims which are unobvious without the percentage limitations. Reconsideration and withdrawal of this rejection is respectfully requested.

With regard to claims 20 and 21 the Examiner alleges that the selection of a NSAID would have been obvious over Lundy et al. The coating agents are allegedly obvious over Lundy et al. in view of Sparks et al. The palatability improving agents are allegedly obvious over Jans et al. Applicants respectfully disagree. The claims are directed to a palatability agent in combination with a coated microparticle. As set forth above, this combination is not rendered obvious by the cited references. The limitation of the drug substance to a NSAID does not render obvious these claims which are unobvious without the NSAID limitation. Reconsideration and withdrawal of this rejection is respectfully requested.

With regard to claim 22 the Examiner alleges that the limitation to a dosage form suitable for administration to a dog or a cat would have been obvious over Lundy et al. The coating agents are allegedly obvious over Sparks et al. The palatability improving agents are allegedly obvious over Jans et al. Applicants respectfully disagree. The claims are directed to a palatability agent in combination with a coated microparticle. As set forth above, this combination is not rendered obvious by the cited references. The limitation to a dosage form suitable for administration to a dog or a cat does not render obvious these claims which are unobvious without such a limitation. Reconsideration and withdrawal of this rejection is respectfully requested.

With regard to claims 24-25 the Examiner alleges that process to prepare Applicants' composition would have been obvious over Lundy et al. in view of Sparks et al., and Jans et al. As set forth above Lundy et al. do not actually describe how to make microparticle compositions. Sparks et al. relate to a matrix composition and not to a coated microparticle composition. Jans et al. do not relate to a controlled release composition. Applicants respectfully submit that

references neither disclose the composition of Applicants' invention nor do they disclose a method of making such a composition. Reconsideration and withdrawal of this rejection is respectfully requested.

With regard to claims 26 and 27 the Examiner alleges that the limitations on the coating percentage would have been obvious over Lundy et al. in view of Sparks et al., and Jans et al.. Applicants respectfully disagree. The claims are directed to a palatability agent in combination with a coated microparticle. As set forth above, this combination is not rendered obvious by the cited references. The addition of the coating percentages does not render obvious these claims which are unobvious without the percentage limitations. Reconsideration and withdrawal of this rejection is respectfully requested.

In view of these remarks and amendments, Applicants respectfully request reconsideration of and withdrawal of all rejections. Allowance of the present application is earnestly requested.

Respectfully submitted,

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